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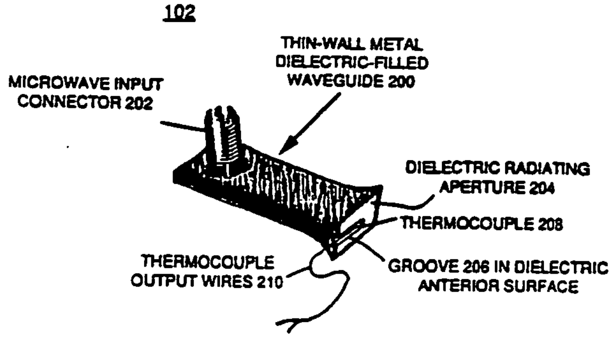
(71) Applicants: MMTC, INC. [US/US]; 12 Roszel Road, Suite A-203, Princeton, NJ 08540 (US). NORTH SHORE UNIVERSITY HOSPITAL RESEARCH CORPORATION [US/US]; 300 Community Drive, Manhasset, NY 11030 (US).

(74) Agent: SELIGSOHN, George, J.; 9367-E Southwest 83 Avenue, Ocala, FL 32676 (US).

(54) Title: THERMOSTATICALLY-CONTROLLED MICROWAVE CYCLODESTRUCTION AS A TREATMENT FOR GLAUCOMA

102



(57) Abstract

A miniaturized microwave applicator comprises a thin-wall metal dielectric-filled waveguide (200) having a thermocouple (208) disposed in a groove (206) in the surface of the dielectric radiating aperture of the waveguide (200). When the aperture is placed in contact with a spot on the outer surface of the sclera overlying the ciliary body to cyclodestruct by heat generated by absorbed microwave energy radiated thereto during a given time, damage due to overheating of the scleral tissue is prevented by the thermocouple (208), which monitors the sclera surface temperature, being used to thermostatically control the microwave energy supplied to the waveguide in a manner that the scleral tissue temperature is maintained substantially constant at a value below that which would cause damage thereto. The desired operation is dependent on the fact that very little of the microwave energy is absorbed by the lower-water-content scleral tissue as it passes therethrough, but is highly absorbed by the underlying high-water-content ciliary-body tissue.

THERMOSTATICALLY-CONTROLLED MICROWAVE CYCLODESTRUCTION AS A TREATMENT FOR GLAUCOMA

BACKGROUND

As known in the art, several different cyclodestruction procedures (i.e., procedures for destroying the ciliary body) have been developed or proposed for treating glaucoma. The clinical standard cyclodestruction procedure employs cryotherapy. Other known cyclodestruction procedures include therapeutic ultrasound and Neodymium:Yag cyclophotocoagulation. However, all of these known cyclodestruction procedures have demonstrated different negative tissue reactions.

Cryotherapy has been characterized by discomfort and edema, therapeutic sound by induced scleral changes, and Neodymium:Yag cyclophotocoagulation has been shown to cause characteristic spot-like conjunctival lesions. Other less specific morbidities have included corneal-scleral thinning, hyphema, cataract, vitritis, retinal detachment, cystoid macula edema, and hypotony. These potential complications have defined cyclodestruction procedures as a last treatment for refractory cases.

SUMMARY OF THE INVENTION

The present invention is directed to a microwave cyclodestruction procedure which avoids negative tissue reactions and minimizes potential complications. The microwaves are applied to the ciliary body by a novel miniature microwave applicator placed in contact with a spot on the outer surface of the sclera. The miniature microwave applicator incorporates a thermocouple on its anterior radiating surface, so that the thermocouple also contacts the spot on the outer surface of the sclera. The thermocouple thermostatically controls the output of

thermostatically control microwave generator 100, prevents microwave energy from being forwarded from the output of microwave generator 100 over transmission line 104 to the input of applicator 102 whenever the temperature of the thermocouple rises to a certain preselected temperature.

Referring to FIGURE 2, applicator 102 comprises thin-wall metal dielectric-filled waveguide.200. In practice, waveguide 200 is fabricated from a block of ceramic material that exhibits a high dielectric constant (e.g., 85) that is machined to the proper size and shape. The longitudinal surface of this properly sized and shaped ceramic material is first electrolessly plated with metal and then electroplated with metal to produce the thin metal wall of waveguide 200. More specifically, the length of waveguide 200 is preferably about one inch; the width of waveguide 200 is preferably about 0.2 inch (i.e., 200 mils); and the thickness of waveguide 200 preferably tapers from about 0.1 inch (i.e., 100 mils) at at its posterior end, to which microwave input connector 202 is attached, to about 0.15 inch (i.e., 150 mils) at its anterior end, which forms dielectric radiating aperture 204. Thus, the area of dielectric radiating aperture 204 is quite small, being only 0.03 square inch.

As shown in FIGURE 2, the dielectric anterior surface, which is preferably flat, has a groove 206 machined therein in which thermocouple 208 is fixedly secured substantially at the center thereof. The thickness of the thermocouple is preferably sufficient to protrude very slightly from the flat dielectric anterior surface. Thermocouple output wires 210, connected to thermocouple 208, extend through the length of groove 206 to the outside of waveguide 200, as shown in FIGURE 2. Thermocouple output wires 210 constitute feedback connection 106 of FIGURE 1.

The therapeutic purpose of applicator 102 in the treatment of glaucoma is to apply sufficient microwave energy to the ciliary body to effect cyclodestruction without creating collateral eye damage. This is accomplished by first positioning 0.03 square inch dielectric radiating aperture 204 in contact with the anterior surface of applicator 102 in contact with a 0.03 square inch spot on the outer surface of the sclera which overlies the ciliary body

e is the base of natural logarithm) of incident microwave energy is absorbed by low-water-content human tissue and by high-water-content human tissue, respectively. It is apparent from this chart that low-water-content human tissue is much more microwave absorbent than high-water-content human tissue. Scleral human tissue is low-water-content human tissue and ciliary-body tissue is high-water-content human tissue. Thus, most of the applied microwave energy merely passes through the thickness of the scleral tissue to be then highly absorbed by the underlying ciliary-body tissue, thereby preferentially heating the underlying ciliary-body tissue.

Referring to the FIGURE 4 chart, there is shown temperature- time duration thresholds for damage to occur in different types of mammalian tissue. As indicated by the wide band of the FIGURE 4 chart, for a given heating duration some types of tissue (e.g., corneal tissue) are damaged substantially less than others. It has been found that both corneal and scleral tissue are not damaged by, and tolerate well, being heated to a temperature up to about 50° C for at least one minute. Therefore, the aforesaid fail-safe thermostatically-controlled therapeutic temperature for a heating duration of scleral tissue for one minute certainly may be set at 50° C, and perhaps even somewhat higher.

Returning to FIGURE 2, the high dielectric constant of the dielectric filling of waveguide 200 of applicator 102 serves two important purposes. First, by reducing the microwave wavelength traveling therein for a given microwave frequency, the size of applicator 102 for transporting that given microwave frequency may be reduced (i.e., miniaturized). Second, the high dielectric constant of the dielectric filling of waveguide 200 more nearly matches the high dielectric constant of the high-water content ciliary body, and, therefore, enhances microwave power transfer from dielectric radiating aperture 204 to the ciliary body. Further, for microwave power transfer purposes, the impedance at the microwave input to applicator 102 at the posterior end of waveguide 200 should closely match that presented by transmission line 104, and the impedance at the microwave output from applicator 102 at dielectric radiating aperture 204

WHAT IS CLAIMED IS:

1. A method for treating glaucoma by cyclodestruction; said method comprising the steps of:

(a) supplying microwave energy to ciliary-body tissue through a given spot on the outer surface of scleral tissue which overlies said ciliary-body tissue;

(b) continuously monitoring the temperature of said given spot; and

(c) thermostatically controlling the supply of said microwave energy in accordance with said continuously-monitored temperature to maintain the temperature of said given spot substantially constant at a preselected value which is below that which would result in damage to said scleral tissue, while permitting the temperature of said ciliary body itself to be raised to a given temperature for a given time by said microwave energy supplied thereto, said given temperature and said given time being sufficient to effect cyclodestruction of said ciliary-body tissue.

2. The method defined in Claim 1, wherein step (a) comprises the step of:

(d) supplying microwave energy to said given spot having a frequency value which readily penetrates the thickness of said scleral tissue with little absorption and reaches a corresponding spot of said underlying ciliary body tissue, where it is readily absorbed.

3. The method defined in Claim 2, wherein said frequency value is in a range of 5,000 to 6,000 MHz.

4. The method defined in Claim 1, wherein said preselected value of said temperature of said given spot is no greater than 50°C.

5. The method defined in Claim 4, wherein said given time is of the order of one minute.

said given dielectric constant of said solid dielectric material has a value in the vicinity of that of water; and

the size of said given area is sufficiently small to permit said dielectric radiating aperture to contact only a given spot of scleral tissue of an eye that overlies substantially solely ciliary-body tissue of said eye.

10. The method defined in Claim 9, wherein:

said solid dielectric material consists of a ceramic block having said given dielectric constant.

11. The method defined in Claim 10, wherein:

said given dielectric constant has a value of substantially 85.

12. The method defined in Claim 10, wherein:

said thin metal wall comprises a metal plating on the surface of said ceramic block.

13. The method defined in Claim 9, wherein:

the size of said given area is substantially 0.03 square inch.

14. The method defined in Claim 9, wherein said microwave input is supplied to said posterior end of said waveguide by transmission means exhibiting a predetermined characteristic impedance; and wherein:

said thin metal wall filled with solid dielectric material has a second given area of a certain size at the posterior end of said waveguide, said certain size being such as to provide said waveguide with an input impedance that substantially matches said predetermined characteristic impedance exhibited by said transmission means.

15. The method defined in Claim 14, wherein:

the size of said second given area is different from that of said first-mentioned given area, and the cross section area of said thin metal wall filled with solid dielectric material tapers in size between said second and first-mentioned given areas.

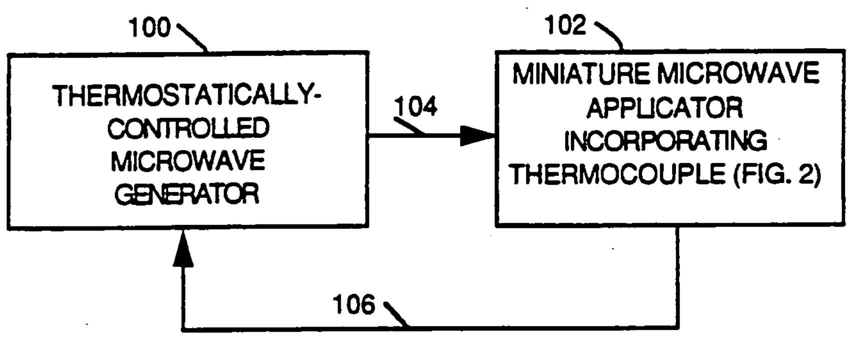

100
THERMOSTATICALLY-CONTROLLED MICROWAVE GENERATOR
104
102
MINIATURE MICROWAVE APPLICATOR INCORPORATING THERMOCOUPLE (FIG. 2)
106

FIGURE 1

102

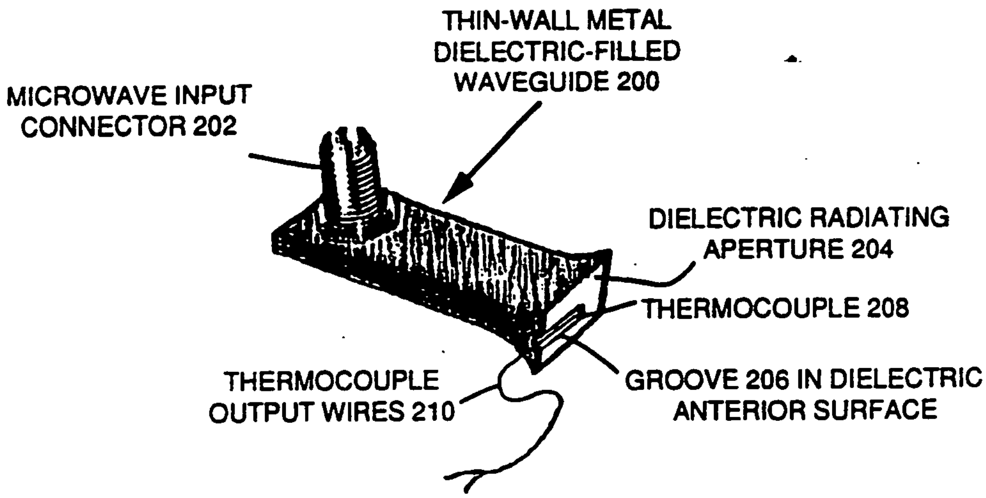

THIN-WALL METAL
DIELECTRIC-FILLED
WAVEGUIDE 200
MICROWAVE INPUT
CONNECTOR 202
DIELECTRIC RADIATING
APERTURE 204
THERMOCOUPLE 208
THERMOCOUPLE
OUTPUT WIRES 210
GROOVE 206 IN DIELECTRIC
ANTERIOR SURFACE

FIGURE 2

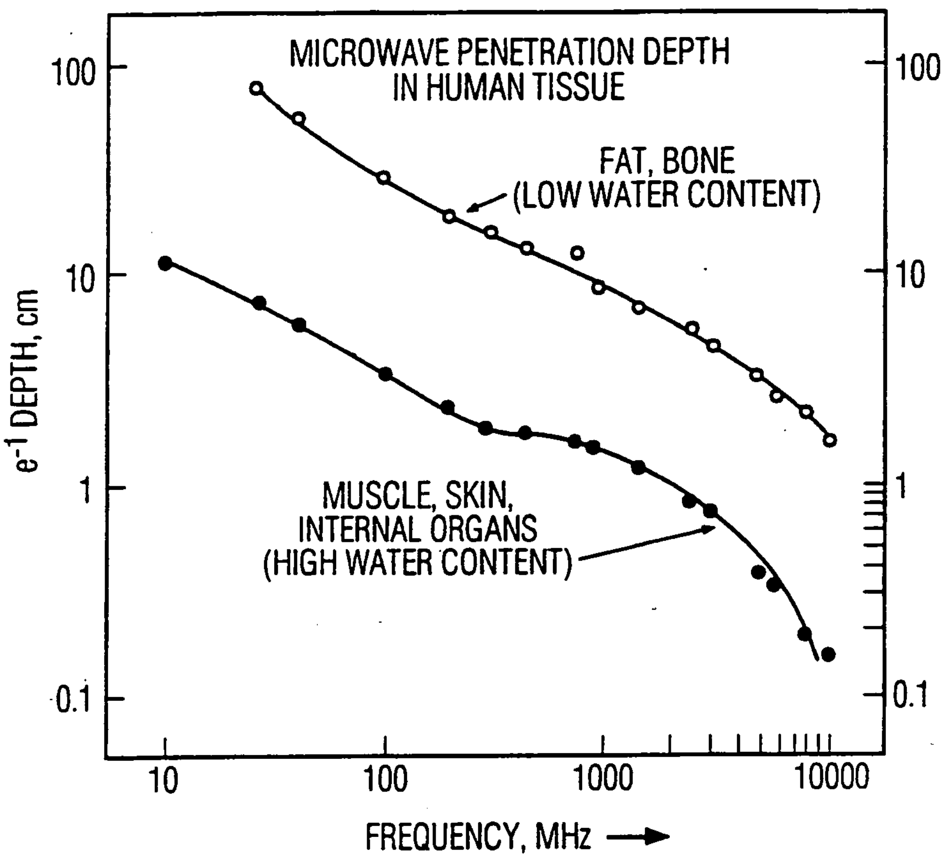
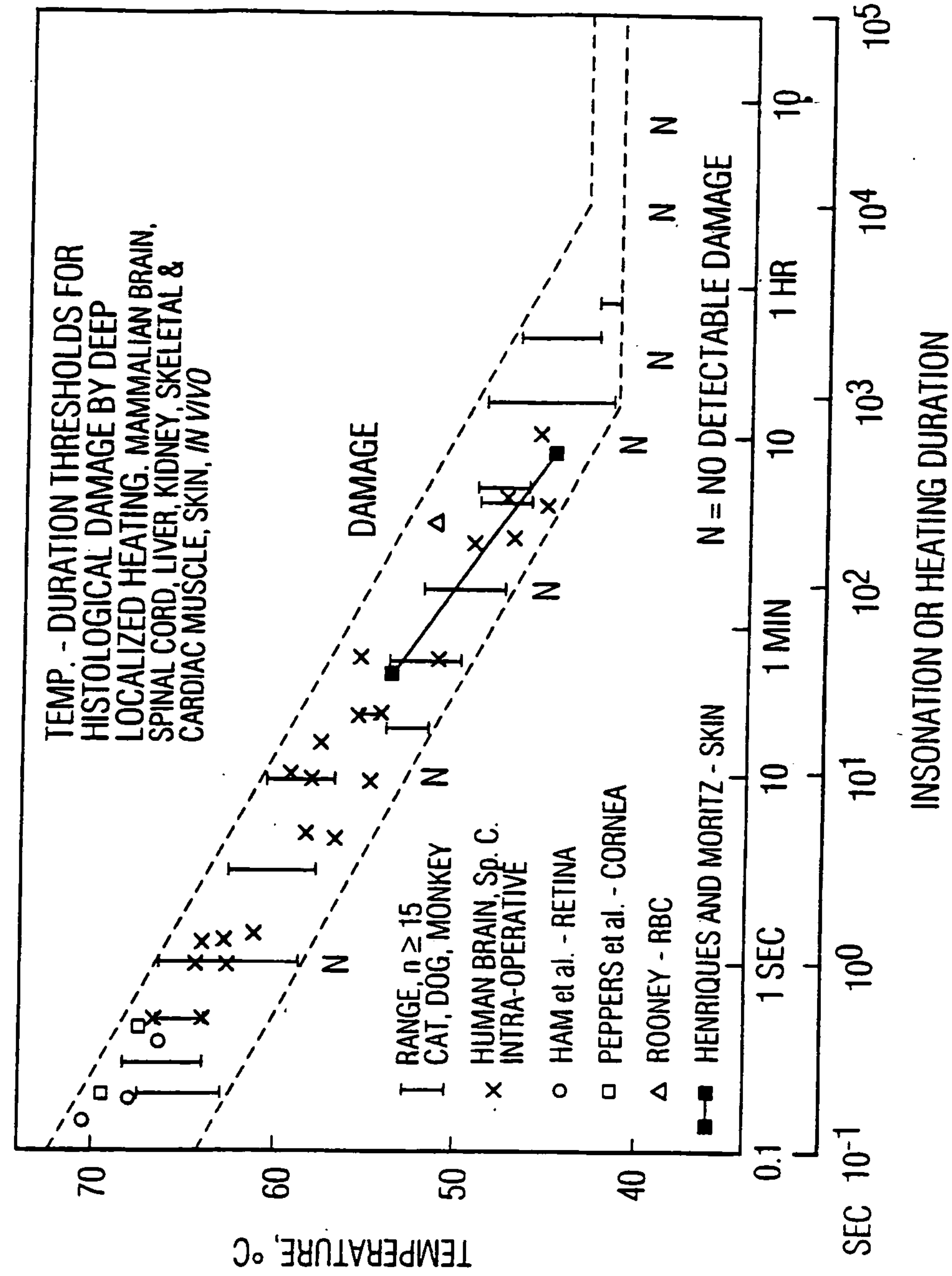

MICROWAVE PENETRATION DEPTH
IN HUMAN TISSUE
FAT, BONE
(LOW WATER CONTENT)
MUSCLE, SKIN,
INTERNAL ORGANS
(HIGH WATER CONTENT)
e-1 DEPTH, cm
100
10
1
0.1
10
100
1000
10000
FREQUENCY, MHz

FIGURE 3

FIGURE 4


TEMP. - DURATION THRESHOLDS FOR HISTOLOGICAL DAMAGE BY DEEP LOCALIZED HEATING, MAMMALIAN BRAIN, SPINAL CORD, LIVER, KIDNEY, SKELETAL & CARDIAC MUSCLE, SKIN, IN VIVO
DAMAGE
N = NO DETECTABLE DAMAGE
N
RANGE, n ≥ 15 CAT, DOG, MONKEY
HUMAN BRAIN, Sp. C. INTRA-OPERATIVE
HAM et al. - RETINA
PEPPERS et al. - CORNEA
ROONEY - RBC
HENRIQUES AND MORITZ - SKIN
TEMPERATURE, °C
70
60
50
40
0.1
1 SEC
10
1 MIN
10
1 HR
10
SEC 10^{-1}
10^0
10^1
10^2
10^3
10^4
10^5
INSONATION OR HEATING DURATION

INTERNATIONAL SEARCH REPORT

International Application No PCT/US92/03425

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): B23K 15/10
US Cl.: 219/10.55B ; 128/804

II FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	219/10.55A, 10.55B, 10.55F, 10.55M ; 73/359R, 355EM 128/399, 413, 736, 784, 788, 800, 804 ; 604/20; 606/3,4,11

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No [13]
X Y	US,A, 4,204,549 (Paglione) 27 May 1980 (See the entire document)	1-2,7,9-10,12, 14-15,17 3-6,8,11,13,16
A	US,A, 4,589,424 (Vaguine) 20 May 1986 (See entire document)	1-17
A	US,A, 4,190,053 (Sterzer) 26 February 1980 (See the entire document)	1-17
A	US,A, 4,271,848 (Turner et al) 09 June 1981 (See the entire document)	1-17
A	US,A, 4,282,887 (Sterzer) 11 August 1981 (See the entire document)	1-17
A	US,A, 4,311,154 (Sterzer et al) 19 January 1982 (See the entire document)	1-17
A	US,A, 4,841,990 (Kikuchi et al) 27 June 1989 (See the entire document)	1-17

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26 June 1992	21 JUL 1992
International Searching Authority	**Signature of Authorized Officer**
ISA/US	Nguyen Ngoc-Ho Fr Tu Hoang NGUYEN NGOC-HO INTERNATIONAL DIVISION